DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94367d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express

Our Reference: 1000123953

October 17, 2003

Henry J. te Velde, D.V.M., President
JVJ Dairy, Inc., AKA Meadow Dairy
8632 Meadow Drive
Winton, CA 95388

WARNING LETTER

Dear Dr. te Velde:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of illegal drug residue in cows that originated from your dairy located at 8632 Meadow Drive, Winton, CA 95388. As a follow-up to USDA's finding, our investigators performed an inspection of your dairy operation September 3 and 4, 2003. This inspection revealed serious violations of Sections 402(a)(2)(C)(ii), 402(a)(4) and 501(a)(5) of the Federal Food, Drug, and Cosmetic Act (the Act). .

On May 15, 2003, you consigned a dairy cow identified with ear tag number [redacted] subsequently identified with back tag number [redacted] and USDA retain tag #[redacted], for slaughter as human food. USDA analysis of tissue samples (USDA laboratory report number 435757) collected from that animal identified the presence of the drug penicillin in the kidney at 0.10 part per million (ppm).

The tolerance level for penicillin in the uncooked edible tissue of cattle is 0.05 ppm (Title 21 Code of Federal Regulations (CFR), Part 556.510). Your use of penicillin in this animal resulted in the illegal drug residue found in the kidney. A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigators noted the following:

1. You lack an adequate system for assuring that drugs are used in a manner consistent with the directions contained in their labeling. For example, the labeling for Han Pen G (penicillin G procaine) prescribes a dosage of 1 ml per 100 pounds of body weight with no more than 10 ml administered at one site. You are administering 25 ml, all at one site, to cattle that average approximately 1350 pounds body weight. In addition, you are failing to follow the labeled directions for the drug Tetrasol Soluble Powder (tetracycline hydrochloride soluble powder). The labeled indication for Tetrasol Soluble Powder is for use in drinking water for calves. You are packing Tetrasol powder in capsules and administering the drug intrauterine for the treatment of retained placentas in dairy cows.

2. You lack an adequate inventory/accountability system for determining the quantities of drugs used to medicate your cows and calves.

3. You fail to maintain complete medication treatment records on the dairy cows. For example, your treatment records fail to include the dosage of the drug administered, the person administering the drugs and the withdrawal times for meat and milk.

You are adulterating Han Pen G (penicillin G procaine) within the meaning of Section 501(a)(5) of the Act, in that it is a new animal drug within Section 201(v) of the Act, and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with its approved labeling. The manufacturer's label prescribes a dosage of 1 ml per 100 pounds of body weight with no more than 10 ml administered at one site. You are administering 25 ml, all at one site, to cattle that average approximately 1350 pounds body weight.

Failure to comply with the label instructions on drugs you use to treat your animals presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use. We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

You should notify our office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Russell A. Campbell, Compliance Officer, United States Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely yours,

Dennis K. Linsley
District Director
San Francisco District